Use of SSRI in pregnancy: Consequences for motor and cognitive development of the child.

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The objective of this study is to examine the consequences of the use of an SSRI in pregnancy for motor and cognitive development of the child, in the short and long term.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON30573

Source
ToetsingOnline

Brief title
SMOK
SSRI Medication in pregnant women: Effect on Development of Children.

Condition

- Movement disorders (incl parkinsonism)
- Neonatal and perinatal conditions
- Developmental disorders NEC

Synonym
motor and cognitive development/ motor and mental development

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: child, development, pregnancy, SSRI

Outcome measures

Primary outcome

In the first week after birth and at 3 months post-term: Quality of general

movements.

At the age of 2 and 6 years: Motor and cognitive development.

Secondary outcome

Not applicable.

Study description

Background summary

Infants of depressed mothers are at increased risk for developing cognitive and motor problems. A major depression often is treated with drugs, also in pregnant women, although the risk of the drug for the fetus is unknown. Approximately 2% of the Dutch pregnant women is using an SSRI (selective serotonin reuptake inhibitor) as antidepressant drug.
SSRI*s cross the placenta easily. The consequences of the use of an SSRI by the mother for the child remain to be determined. Short-term consequences are, among other things, an increased incidence of birth defects, withdrawal symptoms, convulsions, low Apgar score, low birth weight, prematurity, and admission to a neonatal intensive care unit. Long-term effects are insufficiently examined.
Neurotransmitters, especially the ontogenetic *old *ones like serotonin, are detectable in the embryo before the neurons are differentiated. Serotonin is present in the fertilized egg and is involved in the morphogenesis of brain, heart, craniofacial epithelium and other structures. In MAO- knockout mice in which an excessive amount of serotonin is present, normal development of the somatosensor cortex is absent. Both a deficiency as well as an excessive amount of serotonin changes the amount and development of neurons in the brain.
Hypothesis: Regarding the facts that serotonin is involved in synthesis of serotonergic neurons (autoregulation) as well as in the development of target

tissues such as specific parts of the brain, the use of SSRI in pregnancy could lead to problems in the development of the fetus, both structurally as in the case of morphogenesis, and in motor and cognitive development.

Study objective

The objective of this study is to examine the consequences of the use of an SSRI in pregnancy for motor and cognitive development of the child, in the short and long term.

Study design

A prospective controlled design.

Study burden and risks

The tests at the age of 1 week and 3 months concern the observation of spontaneous movements and carry no burden for the child.
The test at the age of 2 years can be judged as a play situation in which the child is invited to show certain skills.
The tests at the age of 6 years are divers and can easily be performed by children of this age.
This research can only be performed with children because it concerns the development of children. These tests carry no risks for the child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Newborn baby exposed to a SSRI in utero.

Exclusion criteria

1. Exposure to an anti-epileptic drug in utero.
2. Simultaneous exposure to a non-SSRI antidepressant as well as a SSRI in utero.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2007
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN53506435
CCMO	NL13159.042.06